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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/529,734 | 06/19/2000 | GILBERT THEO HINZE | 23739 | 3227 |

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| EXAMINER | |
|---|---|
| PAK, JOHN D | |
| ART UNIT | PAPER NUMBER |
| 1616 | |

DATE MAILED: 07/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/529,734 | HINZE |
| **Examiner** | **Art Unit** |
| Pak, J. | 1616 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Apr 15, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *9-19* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *9-19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 9-19 are pending in this application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-13 and 19 depend on the now-canceled claim 2. Therefore the subject mater of claims 11-13 and 19 cannot be determined. Consequently, claims 11-13 and 19 cannot be further examined on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(1) Claim 10 recites an electrochemically activated anion-containing aqueous solution that is (i) substantially pH independent, but (ii) has a redox potential in excess of the redox potential of the receiving water. These two features, (i) and (ii), lack adequate descriptive support from the originally filed disclosure. There is no "pH independent" feature described in the originally filed disclosure, and there is no "receiving water" redox potential disclosure in the originally filed

disclosure. Therefore, the two features noted above were not reasonably conveyed in the originally filed disclosure.

(2) Claim 17 recites a step of atomising the inventive solution for "approximately 2 minutes in every period of 20 minutes." There is no descriptive support for this feature. This feature was not reasonably conveyed in the originally filed disclosure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 7-328628.

JP 7-328628 explicitly discloses separately recovering acidic water from an electrolysis cell, wherein in one embodiment the ORP (i.e. redox potential) is from +600 mv to +700 mv. See the entire document, in particular column 6, paragraph 44. See also the attached English abstract, Chemical Abstract 124:155560.

While the cited reference does not expressly state that the disclosed electrolyzed acidic water with a redox potential of from +600 mv to +700 mv is to be used for treatment of pathogenic microorganisms in a live animal, since the same electrolyzed water is disclosed and nothing about the sterilized water produced by the teachings of the reference indicates that it cannot be administered to a live animal, the same functionality must necessarily be possessed by the disclosed electrolyzed acidic water. Without more, "substantially pH independent" feature cannot be given further weight because it does not specify the scope of "substantially" and "independent." As a result, the acidic pH of the disclosed electrolyzed acidic water is seen to read on this feature. Additionally, having a redox potential in excess of the redox potential of the receiving water (presuming that "receiving water" means the water before electrolysis) is a necessary feature of the disclosed electrolyzed acidic water, which is oxidized and therefore higher in redox potential. For these reasons, the claimed composition is anticipated, and at the very least rendered obvious within the meaning of section 103(a). In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WPIDS abstract 1996-096021.

WPIDS abstract 1996-096021 explicitly discloses "Kront-Anolit 1," which is a commercial product produced by electrochemical activation of an aqueous solution of sodium or potassium chloride. The anolyte is obtained in an electrolyser with a cell having an ion-selective membrane and an additional insulated electrode in the anode chamber, wherein the pH is 6.5-7.0

and redox potential is 900-950 mv. The anolyte solution is used in medicine, as a disinfectant for building interiors, to prevent intestinal and droplet-type infections of bacterial and viral etiology, in cases of candidosis, dermatomycosis, tuberculosis, etc. and also to protect newborn babies and small children from hospital infections. The solution has biocidal activity and is stable on storage for 7 days.

While the cited reference does not expressly state that the disclosed electrolyzed anolyte solution with a redox potential in the range of 900-950 mv is substantially pH independent and its redox potential is in excess of the receiving water redox potential, the claimed composition is still seen to be anticipated or at least rendered obvious by the reference disclosure. Without more, "substantially pH independent" feature cannot be given further weight because it does not specify the scope of "substantially" and "independent." As a result, the pH 6.5-7.0 range of the disclosed electrolyzed anolyte solution is seen to read on this feature. Additionally, having a redox potential in excess of the redox potential of the receiving water (presuming that "receiving water" means the water before electrolysis) is a necessary feature of the disclosed electrolyzed anolyte solution, which is oxidized and therefore higher in redox potential. For these reasons, the claimed composition is anticipated, and at the very least rendered obvious within the meaning of section 103(a). In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bakhir et al. (US 5,427,667).

Bakhir et al. explicitly disclose numerous electrolyzed anolyte solutions that have various pH's and redox potential ranging from 630 to 1200 mv[1] (see columns 9-10, Table 2). Bakhir et al. disclose that it is known to use the anolyte solution from electrolyzed salted water as disinfection solutions in medicine (column 1, lines 38-42).

While the cited reference does not expressly state that the disclosed electrolyzed anolyte solution is to be used for treatment of pathogenic microorganisms in a live animal, since the same electrolyzed anolyte solution is disclosed and nothing about this solution indicates that it cannot be administered to a live animal, the same functionality must necessarily be possessed by the disclosed anolyte solution. Without more, "substantially pH independent" feature cannot be given further weight because it does not specify the scope of "substantially" and "independent." As a result, the acidic pH range of the disclosed electrolyzed anolyte solutions is seen to read on this feature. Additionally, having a redox potential in excess of the redox potential of the receiving water (presuming that "receiving water" means the water before electrolysis) is a necessary feature of the disclosed electrolyzed anolyte solution, which is oxidized and therefore higher in redox potential. For these reasons, the claimed composition is anticipated, and at the very least rendered obvious within the meaning of section 103(a). In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

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[1] Although "mv" unit for ORP (redox potential) is not explicitly spelled out by Bakhir et al., one of ordinary skill in the art would have recognized mv as the standard ORP unit in this field of electrolyzing dilute chloride solutions.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Morrow.

Morrow teaches that electrolyzed sodium chloride is used to treat a host animal for a variety of pathogenic diseases (see from column 3, line 28 to column 5, line 19; Examples I, IV, X-XII, XVI, XVII; claims 1-6). Various modes of administration are disclosed, e.g. intravenous, oral, vaginal, rectal, depending on the condition being treated (column 9, lines 27-31). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorous acid and hypochlorite (see from column 4, line 46 to column 5, line 19; column 9, lines 19-26). Discussion of optional antioxidant to moderate or neutralize the activity of the electrolyzed saline indicates overall oxidizing activity of the electrolyzed saline, which must have a positive redox potential (see e.g., column 5, lines 25-44).

While Morrow does not expressly state in verbatim language that his electrolyzed solution is an "anion containing solution," applicant grossly overestimates the significance of this term (see applicant's argument in paper no. 8, pages 7-8 in particular). Clearly Morrow's solution must be an "anion containing solution," since it contains oxychlorine species, which are anionic. What more is required from applicant's claim language? The invention of claim 9 is anticipated by Morrow.

Claims 9, 10, 14-16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of WPIDS abstract 1996-096021, Bakhir et al. and Morrow in view of Imai, Fraser et al., VETU abstracts 1985-63045, 1988-60359, 1994-62049 and Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology).

WPIDS abstract 1996-096021 explicitly discloses "Kront-Anolit 1," which is a commercial product produced by electrochemical activation of an aqueous solution of sodium or potassium chloride. The anolyte is obtained in an electrolyser with a cell having an ion-selective membrane and an additional insulated electrode in the anode chamber, wherein the pH is 6.5-7.0 and redox potential is 900-950 mv. The anolyte solution is used in medicine, as a disinfectant for building interiors, to prevent intestinal and droplet-type infections of bacterial and viral etiology, in cases of candidosis, dermatomycosis, tuberculosis, etc. and also to protect newborn babies and small children from hospital infections. The solution has biocidal activity and is stable on storage for 7 days.

Bakhir et al. disclose that it is known to use the anolyte solution from electrolyzed salted water as disinfection solutions in medicine (column 1, lines 38-42; see also column 12, lines 15-34). Bakhir et al. explicitly disclose numerous electrolyzed anolyte solutions that have various pH's and redox potential ranging from 630 to 1200 mv[2] (see columns 9-10, Table 2). The apparatus for electrolysis contains vertical coaxial cylindrical and rod electrodes mounted in dielectric sleeves, a ceramic diaphragm coaxially mounted in sleeves between said electrodes and dividing the electrode spacing into electrode chambers, and appliances for supply and discharge of

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[2] Although "mv" unit for ORP (redox potential) is not explicitly spelled out by Bakhir et al., one of ordinary skill in the art would have recognized mv as the standard ORP unit in this field of electrolyzing dilute chloride solutions. See also U.S. Patent No. 5,871,623, from line 32 of column 5 to line 7 of column 6, which confirms the mv unit for the disclosure applied herein.

the water being treated (paragraph bridging columns 2 and 3). Separate collection of anolytes and catholytes is effected (column 7, last paragraph).

Morrow teaches that electrolyzed sodium chloride is used to treat a host animal for a variety of pathogenic diseases (see from column 3, line 28 to column 5, line 19; Examples I, IV, X-XII, XVI, XVII; claims 1-6). Various modes of administration are disclosed, e.g. intravenous, oral, vaginal, rectal, depending on the condition being treated (column 9, lines 27-31). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorous acid and hypochlorite (see from column 4, line 46 to column 5, line 19; column 9, lines 19-26). Morrow also discloses the well known fact that products resulting from electrolysis of saline solutions have long been known as in vitro microbicides, and have been used to keep water free of pathogenic organisms such as E. coli (see from column 5, line 56 to column 6, line 19). Discussion of optional antioxidant to moderate or neutralize the activity of the electrolyzed saline indicates overall oxidizing activity of the electrolyzed saline, which must have a positive redox potential (see e.g., column 5, lines 25-44).

Imai discloses 10-100 ppm solutions of hypochlorite that have particle size range of 70-150 microns, which are sprayed to open areas, foodstuffs, as well as to people without damage to materials or eyes, for the control of cholera epidemics (see the entire document, in particular claims 1-6).

Fraser et al. discloses that intestinal diseases in pigs can be caused by a variety of microorganisms (p. 190). Chlorine compounds such as hypochlorite are known to be used as disinfectants, particularly for disinfecting water supplies (p. 1530).

VETU abstract 1985-63045 discloses the use of sodium hypochlorite to disinfect swine pens to prevent diseases. VETU abstract 1988-60359 teaches the importance of disinfectants in preventing coccidiosis in neonatal pigs. VETU abstract 1994-62049 discloses the benefit of water disinfection as part of a therapy regimen to control infections of E. coli, Newcastle disease, and infectious bursal disease in broiler flocks.

The article by Kroschwitz et al. is cited to establish that the electrochemical reactor features of the instant invention is conventional electrolysis technology that would have been within the skill of the ordinary skilled artisan in this field (see pp. 124-133, 135-140). Various oxychlorine species are disclosed upon electrolysis of a chloride solution (pp. 133-135). m

The cited references suggest the claimed invention. Morrow establishes that sodium chloride solution that has been electrolyzed to produce effective amounts of oxychlorine species and ozone is safe to administer to a live animal via intravenous, oral, vaginal or rectal modes of administration. While Morrow does not expressly state in verbatim language that his electrolyzed solution is an "anion containing solution," applicant grossly overestimates the significance of this term (see applicant's argument in paper no. 8, pages 7-8 in particular). Clearly Morrow's solution must be an "anion containing solution," since it contains oxychlorine species such as hypochlorite, which are anionic. Although Morrow does not explicitly state that the electrolyzed

solution must be the anolyte solution, both Bakhir et al. and WPIDS abstract 1996-096021 make it clear that it is the anolyte solution that has the microbicidal activity. WPIDS abstract 1996-096021 further teach that an anolyte of electrolyzed aqueous solution of sodium or potassium chloride can be used to disinfect building interiors, prevent intestinal infections of bacterial and viral etiology, treat cases of candidosis, dermatomycosis, tuberculosis, etc. and protect newborn babies and small children from hospital infections. Thus, one having ordinary skill in the art would have been motivated to use a solution of electrolyzed salt solution such as sodium chloride, anolyte solution in particular, to treat pathogenic microorganisms in a live animal with the expectation that the treatment solution would be safe and effective as a microbicidal agent.

Additionally, given the known methods by which pathogens are spread by contact and inadequate hygienic conditions, in view of the known practice of spraying hypochlorite solution to control cholera (intestinal disease caused by a pathogenic microorganism), adding chlorine compounds such as hypochlorite to water supplies to control various animal diseases, and disinfecting with hypochlorite solution to prevent diseases, one having ordinary skill in the art would have been motivated to utilize the electrolyzed salt (e.g. sodium chloride) solution of the instant claims, which contains active oxychlorine species such as hypochlorite, as an oral, atomizing or soaking/rinsing/dipping agent to control pathogenic microorganisms in a live animal, including respiratory (e.g. tuberculosis, see WPIDS abstract 1996-096021) and gastrointestinal pathogenic microorganisms. Introduction to drinking water is suggested from the explicit oral

administration teaching and the known such use for hypochlorite. Droplet size of 5-100 μm is suggested from the overlapping droplet size range of 70-150 μm for hypochlorite (Imai).

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.

Applicant's arguments, filed in paper no. 8 (4/15/02) have been given due consideration in this regard but applicant's points are rendered moot by the newly applied references and the new ground of rejection.

For these reasons, all claims are refused again.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600